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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/364,343	07/30/1999	JACQUELINE R. DOYLE	KJ-100	9327

7590

02/07/2002

ARTHUR A SMITH JR
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BOSTON, MA 02109

EXAMINER

MENDEZ, MANUEL A

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 02/07/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

restart time

Office Action Summary

Application No.

09/364,343

Applicant(s)

Doyle, et al.

Examiner

Manuel Mendez

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 16, 2001
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Response to Amendment

1. The amendment filed November 16, 2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The introduction of the term - - **non-invasive** - - into the specification of this application is considered new matter. In response to Applicant's comments, according to claim 1, the claimed invention is a "dispenser" and not a **wound irrigation and and debriding system** . Moreover, the term "wound irrigation and and debriding system is not positively disclosed in claim 1. Therefore, it appears that the addition of this term intends to change the scope of the claim and its supporting specification.

Applicant is required to cancel the new matter in the reply to this Office action.

2. Applicant's arguments filed November 16, 2001 have been fully considered but they are not persuasive. Examiner has reviewed the amendments made to claim 1 and concluded that said amendments do not overcome the rejection presented under section 102(b). In relation to the term "one-piece", the court in **In re Larson**, 340 F.2d 965, 144 USPQ 347, 349 (CCPA 1965), clearly stated that the difference between a one-piece or a multiple piece design is an obvious design choice. Therefore, the term "one piece" does not add any patentable weight to the claim.

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Additionally, the phrases "non-invasive" and "which is disposable in any container" are considered intended uses of the dispenser. The court in In re Casey, 152 USPQ 235 (CCPA1967), clearly stated that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. The phrases cited above do not result in any structural difference, and therefore, do not overcome the 102(b) rejection.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

4. **Claims 1, 3, 4, and 5** are rejected under 35 U.S.C. 102(b) as being anticipated by **Hussey**. The referenced patent shows in figures 1-6, a flexible chamber (1, 10) having an internal volume containing enema fluid (which is considered a sterile solution), the chamber having an orifice, a nozzle (15) having a first opening at one end and a second opening at the other end, wherein the first opening is affixed to the orifice of the chamber and the second opening dispenses the enema fluid, a protective tip (20) affixed to the second opening of the nozzle maintaining the solution in a sterile state, and a removable packaging band (30) around the protective tip. In

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relation to **claims 3 and 4**, figure 1 shows a screw-on cap to affix the first opening to the orifice of the chamber, and figure 2 shows a one-piece enema unit. In relation to **claim 5**, figures 1 and 2 both disclose a straight nozzle.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claim 2** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Hussey in view of Reddick**. Hussey does not disclose the use of a filter located in the first opening of the nozzle. However, the use of filters in nozzles is conventional as evidenced by the teachings of Reddick. In figure 2 of the Reddick patent, items 45 and 28 are filters located in the first opening of the nozzle. Based on the above observation, it would have been obvious to modify Hussey by enhancing nozzle (15) with a filter as taught by Reddick, since Reddick suggests in column 5, lines 63-67, that the filters can be used to remove particulate matter and bacteria from the sterile solution, and therefore eliminating the possibility of infections.

7. **Claim 6** is rejected under 35 U.S.C. 103(a) as being unpatentable over Hussey in view of Rose. Hussey does not disclose an angled nozzle. However, the design of an angled nozzle is conventional as evidenced by the teachings of Rose. Rose shows in figures 6-8, various nozzle

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designs with variations in the angular deployment. **Based on the teachings of Rose, a person of ordinary skill in the art would consider the use of angled nozzles, an obvious design choice.**

8. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hussey in view of Wallace, et al. Hussey does not disclose a dispenser having a sterile solution containing sodium chloride and/or distilled water. Examiner would like to point out that all the references utilized in this action are capable of infusing substances containing the disclosed percentages of sodium chloride and/or distilled water. Therefore, since the structure of Hussey is capable of infusing said specific concentrations, the subject matter of claims 7 and 8 is considered to be inherent.

Additionally, Wallace, et al., demonstrates that it is conventional to use dispensers with nozzles to infuse substances with various concentrations of sodium chloride and distilled water. Based on the teachings of Wallace, et al., a person of ordinary skill in the art would have certainly considered an obvious design alternative the use of the dispenser of Hussey in combination with any fluid concentration. The fact that the applicant elected to claim 0.9 percent USP sodium chloride and/or 0.9 percent distilled water does not per se makes the claims patentable since it is well known that a dispenser can be utilized to infuse any substance and concentration thereof.

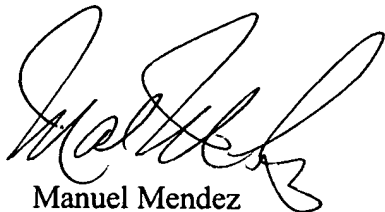
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Conclusion

2. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Mendez whose telephone number is (703) 308-2221.

A handwritten signature in black ink, appearing to read 'Manuel Mendez', with a stylized flourish at the end.

Manuel Mendez

November 29, 2001